



ANALYSIS CERTIFICATE

Lot: 0061112

FDA Labeler Code No. 053296

PRODUCT: MEXILETINE HCl USP

Certificate of Analysis No. : 12A0236/04

Lot No. : A-120221

Quantity. : 10 KG

ANALYTICAL DATA	SPECIFICATIONS	RESULTS	NOTES
Description	White or almost white crystalline powder.	Conforms	
Identification	Test A.- I.R., Test B.- TLC and Test C.- Ch	Conforms	
pH	3.5 - 5.5	5.0	
Loss on Drying	NMT 0.5%	Less than 0.05 %	
Residue on ignition	NMT 0.1%	Less than 0.05 %	
Heavy Metals	NMT 0.001% (Pb)	Conforms	
Chromatographic purity. Any individual impurity	NMT 1.0%	0.01 %	
Chromatographic purity. Total impurities	NMT 1.5%	0.03 %	
Assay	98.0 - 102.0% (on dry basis)	100.1 %	

Manufacturing Date June 27, 2012

Re-Test date June 27, 2015

Analyst

Quality Control Manager

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